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08/786,937	01/22/1997	PHILIPPE BOUCHARD	098501-0235299	5859	
999 7590 PILLSBURY WINTHROP SHAW PITTMAN, LLP P.O. BOX 10500			EXAM	EXAMINER	
			BORGEEST, CHRISTINA M		
MCLEAN, VA	A 22102		ART UNIT	PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 08/786.937 BOUCHARD ET AL. Office Action Summary Examiner Art Unit Christina Borgeest 1649 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 23 April 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) See Continuation Sheet is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) See Continuation Sheet is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) ____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on 22 January 1997 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner, Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some * c) ☐ None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date. Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application 3) Information Disclosure Statement(s) (PTO/SB/08)

Paper No(s)/Mail Date

6) Other:

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Continuation of Disposition of Claims: Claims pending in the application are 38,39,42,44-51,56-63,67-70,72-75,78-80,83,84,86-92,94-100,102-105,107,108,110-116,118,119,121-123 and 126-141.

Continuation of Disposition of Claims: Claims rejected are 38,39,42,44-51,56-63,67-70,72-75,78-80,83,84,86-92,94-100,102-105,107,108,110-116,118,119,121-123 and 126-141.

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 April 2009 has been entered.

Formal Matters

The amendment filed 23 April 2009 is acknowledged. Claims 38, 51, 61, 83, 92, 99 and 115 are currently amended. Claims 38, 39, 42, 44-51, 56-63, 67-70, 72-75, 78-80, 83, 84, 86-92, 94-100, 102-105, 107, 108, 110-116, 118, 119, 121-123, and 126-141 are under examination.

Rejections Maintained/New Rejections

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 38, 39, 42, 44-51, 56-63, 67-70, 72-75, 78-80, 83, 84, 86-92, 94-100, 102-105, 107, 108, 110-116, 118, 119, 121-123, and 126-141 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 38, 39, 42, 44-51, 56-63, 67-70, 72-75, 78-80, 83, 84, 86-92, 94-100, 102-105, 107, 108, 110-116, 118, 119, 121-123, and 126-141 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are as follows. First, there is no recitation of a patient population. The claims do not recite on whom the methods are being performed. Second, although independent claims 38 and 51 recite the phrase, "throughout the treatment period" (for example, claim 38, line 6), no period of time during which treatment occurs is defined in these claims, nor in any of the dependent claims in the instant application. For instance, the claims recite multiple dosing regimens of different hormones occurring during different days of the menstrual cycle, but it is not clear whether the treatment period encompasses administration of all the hormones over the period of a single assisted reproduction cycle, or only until ovulation induction is achieved or even until pregnancy is achieved. The claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant (see MPEP 2171). Given that the claims are to methods of treatment, a defined treatment period must be clearly articulated in the claims.

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Claims 38, 39, 42, 44-51, 56-63, 67-70, 72-75, 78-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The independent claims recite the phrase "wherein the LHRH antagonist is administered in a single or dual dosage regimen [of a given amount of milligrams of LHRH antagonist] per dose beginning on menstruation cycle day 1 to 10." It is not clear whether Applicants are claiming a single or dual dosage regimen of the recited milligrams per dose *per day* on menstruation cycle day 1 to 10, or alternatively, per hour or some other unit of undefined time measurement. Claims 44, 45, 56, 57, 67, 68, 78 and 79 recite administration from either cycle days 4 to 8 (claims 44, 56, 67, 78) or 6 to 10 (claims 45, 57, 68, 79), but again, given the recitation of "a single or dual dosage regimen [of a given amount of milligrams of LHRH antagonist] per dose beginning on menstruation cycle day...", the claims still read on an undefined amount of multiple doses during a given period of days. The claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant (see MPEP 2171).

Claims 38, 39, 42, 44-51, 56-60 are rejected are under 35 U.S.C. 112, second paragraph, as being indefinite. When referring to administration of LH and FSH or hMG, the independent claims recite the phrase, "wherein the dose...remains the same during throughout the treatment period", however it is not clear what Applicants are claiming, for instance is a pump inserted to maintain a steady state of hormones in the blood or is an equivalent dose of hormones administered on a daily basis for some undefined period of time. This is further complicated by the issue raised with respect to

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the recitation of the undefined "treatment period", which is raised as an issue in the preceding paragraph. The claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant (see MPEP 2171).

Claims 46 and 132 recite the limitation "a second dose of the LHRH antagonist".

There is insufficient antecedent basis for this limitation in the claims because claims 38 and 129 (from which claims 46 and 132 depend) do not recite a "second dose" but rather recite "wherein the LHRH antagonist is administered in a single or dual dosage regimen..." The broadest reasonable interpretation of this phrase is daily injections of LHRH antagonist occurring beginning on menstruation cycle day 1 through menstruation cycle day 10.

Claims 61-63, 65, 67-70, 72-75 and 78-80, 99, 100, 102-105, 107-108, 110-114 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Independent claim 61 recites "[a] method for obtaining the production of a fertilizable oocyte within a program of COS/ART comprising..." followed by steps (a) and (b), which recite administration of a hormone and a hormone antagonist, respectively, followed by the phrase "ovulation occurs normally between day 9 and 20 of the menstruation cycle without the administration of a hormone or hormone agonist to induce ovulation." This is indefinite because the goal of the claim is to produce a fertilizable oocyte, which requires a successful ovulation, and includes steps requiring administration of

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hormones followed by the negative limitation that no hormone is used to induce ovulation. It is not clear what Applicants are claiming. The negative limitation reciting that no hormone is used to induce ovulation conflicts with step (a) of the claim. The dependent claims, 62, 63, 65, 67-70, 72-75 and 78-80, do not remedy the problem.

Claims 83, 84 and 86-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Claim 83 recites administration of the LHRH antagonist in step (b) in a daily dose of 0.25 mg/day for multiple days, followed by the wherein clause that the LHRH antagonist is administered daily on menstruation cycle 1 to 10 (or started on cycle day 4 to 8 in claim 86) and ovulation occurs between day 9 and 20 of the menstruation cycle. If the antagonist is administered on day 8 or 9, and ovulation occurs on day 9 or 10, then the LHRH antagonist is not administered for multiple days, as required by the claims.

Claim Rejections - 35 USC § 112, first paragraph - New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47, 59, 61-63, 65, 67-70, 72-75, 78-80, 89, 97, 99-100, 102-105, 107-108, 110-114 and 121 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

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was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims contain the negative limitation "without the administration of a hormone or hormone agonist to induce ovulation." The specification and claims as originally filed in 22 January 1997 do not contain any suggestion of omission of hCG or a hormone agonist to induce ovulation. There is the suggestion at p. 4, lines 10-12 of the use of other ovulation inducing agents other than hCG resulting in reduced ovarian hyperstimulation syndrome, but there is no suggestion of *not* administering any hormone or hormone agonist to induce ovulation. This negative limitation first appeared in the claim amendments filed 3 August 2004. Applicants submitted in their remarks dated 3 August 2004 that support for the amendments could be found in p. 5, lines 14-19 of the specification and original claims 7 and 10. However, neither the passage from the original specification nor original claims 7 and 10 make any mention of *not* administering any hormone or hormone agonist to induce ovulation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

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The rejection of claims 38, 39, 42, 44-46, 48-51, 56-58 and 60 under 35 U.S.C. 102(b) as being anticipated by Diedrich et al. (cited in previous Office actions, mailed 23 October 2008, 13 September 2006, 15 May 2007 and 20 February 2008) is maintained for reasons of record and the following.

Applicants argue at p. 15, 2nd paragraph that in the present invention a single dose of an LHRH antagonist is administered, or optionally a second dose may be administered and that in contrast, Diedrich teaches daily doses of and LHRH antagonist starting at day 7 and continuing until day 14.

This argument has been fully considered but is not found persuasive. Applicants are arguing limitations not present in the claims. As stated above under Rejections under 35 U.S.C. 112, 2nd paragraph, the broadest reasonable interpretation of the phrase "wherein the LHRH antagonist is administered in a single or dual dosage regimen of 3 mg per dose beginning on menstruation cycle day 1 to 10" is daily injections of either one or two 3 mg doses of LHRH antagonist occurring beginning on menstruation cycle day 1 through menstruation cycle day 10, thus in their present incarnation, the claims also read upon multiple daily doses. See MPEP 2106, regarding proper claim interpretation:

USPTO personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. In re Morris, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim should not be read into the claim. E-Pass Techs., Inc. v. 3Com Corp., 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) (claims must be interpreted "in view of the specification" without importing limitations from the specification into the claims unnecessarily). In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969). See also In re Zletz, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) ("During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow.... The reason is simply that during

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patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed... An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.").

With regard to the teachings of Diedrich, they actually state, "15 patients were treated with Cetrorelix at a dose of 3 mg daily starting on day 7 of the menstrual cycle until ovulation was induced." In other words the endpoint of the daily dosing was not reported and ovulation has been known to occur before menstruation day 14.

Furthermore, the claims recite that ovulation occurs between days 9 and 20, thus this is encompassed by the prior art because LHRH antagonist dosing could start on day 7 and ovulation could occur on day 9.

Applicants argue at p. 16, 2nd paragraph that Diedrich et al. does not "disclose a method whereby the levels of FSH secretion are not suppressed." And that "to the extent Diedrich data may speak to this question, Diedreich notes that a decrease in FSH was observed in the luteal phase."

The issue remains that the recited method steps do not distinguish over the prior art. First, as noted above, the Examiner must give the claims their broadest reasonable interpretation. The claims recite "wherein said amount of LHRH antagonist does not suppress endogenous FSH secretion, which is maintained at a natural level..." but no treatment period for the entire protocol is ever defined in the claims or the specification. Second, given that the claims also recite that the LHRH antagonist is administered beginning on menstruation cycle day 1 to 10, and that this amount of LHRH antagonist does not suppress endogenous FSH secretion, the most reasonable interpretation of the claims is that FSH levels remain natural during the follicular phase of the cycle

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(encompassing the dosing period of menstruation day 1-10). FSH levels naturally fall during the luteal phase of a normal cycle, therefore, the observation of Diedrich et al. that a decrease in FSH was observed in the luteal phase is not at all surprising, nor does it teach against the recitation in the claims. (Specifically, note that Diedrich et al. teach at p. 790, left column, 3rd paragraph that "only in the luteal phase was a decrease in FSH seen.") The luteal phase spans from ovulation at about midcycle until menstruation, so given that the treatment period in the amended claims is still undefined, it is not clear at what time-point in the instant method steps FSH must be maintained at its natural level. In summary, the most reasonable interpretation of the claims given the lack of defining treatment period is that endogenous secretion of FSH is not suppressed during the period of time where LHRH antagonist is administered, in other words, the follicular phase of the cycle. Since it is normal for FSH levels to fall during the luteal phase, and because the claims do not recite the period of time during which endogenous FSH is not suppressed, than the claims are encompassed by the teachings of Diedrich.

The rejection of claims 38, 39, 42, 44-46, 48-51, 56-58 and 60 under 35

U.S.C. 102(a) as being anticipated by Olivennes et al. (Human Reprod. 1995; 10: 1382-1386) as set forth in the previous Office action mailed 20 February 2008 is maintained for reasons of record and the following.

Applicants argue at p. 15, last paragraph that inventors Bouchard and Frydman are co-authors of the Olivennes publication, and that the reference publication is related to the research project that gave rise to the present invention and therefore is

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disqualified as a reference because it is a publication of inventors own work (and they cite MPEP 715.01(c) and 706.01(c), citing In re Katz.)

This argument has been fully considered but is not found persuasive. The inventors of the instant application are Bouchard, Frydman, Deroey, Diedrich and Engel. The authors of the Olivennes publication are Olivennes, Fanchin, Bouchard, Taïeb, Selva and Frydman. The instant application and the Olivennes publication have three authors in common; the instant application has three authors not listed on the Olivennes publication and finally, the Olivennes publication has four additional authors not listed as inventors on the instant application, thus this publication does qualify as being "by another" under 35 U.S.C. 103(a). See MPEP 2132 35 U.S.C. 102(a)

III. "BY OTHERS"

"Others" Means Any Combination of Authors or Inventors *Different Than the Inventive Entity*. The term "others" in 35 U.S.C. 102(a) refers to any entity which is different from the inventive entity. *The entity need only differ by one person* to be "by others." This holds true for all types of references eligible as prior art under 35 U.S.C. 102(a) including publications as well as public knowledge and use. (Emphasis added).

The MPEP 2132 provides guidance as to the proper way to overcome a rejection under 35 U.S.C. 102(a):

APPLICANT CAN REBUT PRIMA FACIE CASE BY SHOWING REFERENCE'S DISCLOSURE WAS DERIVED FROM APPLICANT'S OWN WORK

Applicant's disclosure of his or her own work within the year before the application filling date cannot be used against him or her under 35 U.S.C. 102(a). In re Katz, 687 F.2d 450, 215 USPQ 14 (CCPA 1982) (discussed below). Therefore, where the applicant is one of the co-authors of a publication cited against his or her application, the publication may be removed as a reference by the filling of affidavits made out by the other authors establishing that the relevant portions of the publication originated with, or were obtained from, applicant. Such affidavits are called disclaiming affidavits. Ex parte Hirschler, 110 USPQ 384 (Bd. App. 1952). The rejection can also be overcome by

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submission of a specific declaration by the applicant establishing that the article is describing applicant's own work. In re Katz, 687 F.2d 450, 215 USPQ 14 (CCPA 1982). However, if there is evidence that the co-author has refused to disclaim inventorship and believes himself or herself to be an inventor, applicant's affidavit will not be enough to establish that applicant is the sole inventor and the rejection will stand. Ex parte Kroger, 219 USPQ 370 (Bd. Pat. App. & Int. 1982) (discussed below). It is also possible to overcome the rejection by adding the coauthors as inventors to the application if the requirements of 35 U.S.C. 116, third paragraph are met. In re Searles, 422 F.2d 431, 164 USPQ 623 (CCPA 1970). (Emphasis added).

And:

A 37 CFR 1.131 AFFIDAVIT CAN BE USED TO OVERCOME A 35 U.S.C.

102(a) REJECTION

When the reference is not a statutory bar under 35 U.S.C. 102(b), (c), or (d), applicant can overcome the rejection by swearing back of the reference through the submission of an affidavit under 37 CFR 1.131. In re Foster, 343 F.2d 980, 145 USPQ 166 (CCPA 1965). If the reference is disclosing applicant's own work as derived from him or her, applicant may submit either a 37 CFR 1.131 affidavit to antedate the reference or a 37 CFR 1.132 affidavit to show derivation of the reference subject matter from applicant and invention by applicant. In re Facius, 408 F.2d 1396, 161 USPQ 294 (CCPA 1969). See MPEP § 715 for more information on when an affidavit under 37 CFR 1.131 can be used to overcome a reference and what evidence is required. 2133 35 U.S.C. 102(b)

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vagel, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 38-39, 42, 45-51, 56-63, 65, 67-70, 72-75, 78-80, 83, 84, 86-92, 94-100, 102-105, 107, 108, 110-116, 118, 119, 121-123, 126-141 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent 7,393,834 is maintained for reasons of record.

Note, that because the claims of the 10/661,789 application are now patented as claims 1-21 of U.S. Patent 7,393,834, this rejection is no longer provisional. Applicants' request of deferral of this issue until other issues of patentability are resolved in their response filed 23 April 2009 is noted. However, deferral of arguments is not proper; an argument after the claims have been found otherwise allowable that obviousness type double patenting does not exist will not be considered timely. Accordingly, the rejection is maintained. Applicants are encouraged to submit a terminal disclaimer at Applicants earliest convenience.

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Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is (571)272-4482. The examiner can normally be reached on 9:00am - 3:00

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Borgeest

/Bridget E Bunner/ Primary Examiner, Art Unit 1647